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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,426	08/01/2003	Bernhard Kaltenboeck	35721/265190	4998

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EXAMINER	
GRASER, JENNIFER E	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,426	KALTENBOECK ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/31/03*. (previously mailed)
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant requested another copy

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The Examiner of Record has changed from Tammy Field to Jennifer Graser.

1. Acknowledgment and entry of the Amendment submitted on 7/22/04 is made. Claims 1-9 are currently pending.

Claim Rejections - 35 USC § 112

2. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it is unclear what is meant by the new limitation "a particular mouse strain and identifying whether said strain is a low nitric oxide (NO) responder strain or a high NO responder strain". The claim does not state what the nitric oxide is response to. The claim should be amended to recite "selecting a particular mouse strain and identifying whether said strain is a low nitric oxide (N) responder strain or a high NO responder strain when said strain is exposed to Chlamydial antigens". Without the limitation "when exposed to Chlamydial antigens' , it is unclear how one would identify whether the strain is a high NO responder or a low NO responder. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The

claims as they stand are incomplete and fail to provide adequate description to allow for one to identify what is being claimed.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps which makes the claim vague and indefinite. See MPEP § 2172.01. The omitted steps are: the claim fails to state when a mouse would be given a feeding regimen with appropriate levels of arginine and when one would give a mouse an inhibitor of nitric oxide synthase-2. Part (c) and part (d) of the claim should be amended so that instead of the phrase "if appropriate" the claims recite "if the mouse strain is a low nitric oxide responder selecting a feeding regimen..." and "if the mouse is a high nitric oxide responder treating said mouse with an inhibitor of nitric oxide syntase-2..". The claims as written do not represent a complete method because it is unclear when it would be "appropriate" to feed/treat a mouse with the recited regimens. The claim must positively state when either of the regimens are used as the term "if appropriate" is vague and indefinite, e.g., claim 4 should be incorporated into claim 1. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate description to allow for one to identify what is being claimed.

Claim 1 is vague and indefinite because part (B) recites 'selecting a dose of *Chlamydia* to be administered to a test mouse of said strain' and part (e) recites "administering *Chlamydia* to said test mouse" making it unclear whether the *Chlamydia*

is actually administered in part (b) or just "selected" and it is also unclear whether these are the same *Chlamydia*. Clarification and/or correction is required.

Part (f) of claim 1 is vague and indefinite because the specification teaches that when a prophylactic treatment is used the prophylactic has to be administered prior to the administration of the *Chlamydia*. Instant claim 1 has the prophylactic being administered *after* the *Chlamydia*. It is unclear how this would work.

The last three lines of claim 1 are vague and indefinite because it recites that the reference mouse did not receive prophylactic or therapeutic treatment yet it is unclear whether the reference mouse received the same feeding regimen and is the same strain of mouse as the test mouse. The claim does not clarify this. Are all of the parameters for the reference mouse and test mouse identical minus the treatment/prophylactic step, e.g., they are the same strain, same NO responder, receive same feeding regimen and same exposure to *Chlamydial* antigens? The claim does not correlate the evaluation with the final step. What does the severity of disease indicate? Further, it appears that it is the diet which is being assessed not solely the vaccine/immunogen (prophylactic treatment/therapeutic treatment) which is how the claim is written. Clarification/correction is required.

Claim 5 is vague and indefinite because it recites that the feeding regimen requires feeding said mouse a diet high in arginine following prophylactic treatment. However, claim 1 allows for use of a high NO responder strain. Accordingly, it is unclear why one would feed a high NO responder mouse strain a diet high in arginine as encompassed by claim 5. The claim should include the limitation "wherein said

mouse is a low NO responder strain and wherein said feeding regiment requires feeding said mouse a diet high in arginine....". Correction is required.

Claim 6 should add a correlation step which states when such feeding regimen should be added since the regimen will not work with certain some of the test strains recited in claim 1.

Rejections which have been overcome:

2. The Declaration pursuant to *In Re Katz*, has effectively overcome the former 35 USC 102(a) rejection of Huang et al. Applicants' amendments and arguments have effectively overcome the former 112, first enablement rejections and the 102(b) rejections of Campbell et al and Yang et al.

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

4. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 872-9306 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

J Graser 10/5/04

Jennifer Graser
Primary Examiner
Art Unit 1645